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DOCKET NO. PRES06-00181 **PATENT**
Customer No. 23990

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	RONALD A. SCHACHAR, ET AL.
U.S. Serial No.	:	10/080,877
Filed	:	February 22, 2002
For	:	SYSTEM AND METHOD FOR MAKING INCISIONS FOR SCLERAL EYE IMPLANTS
Group No.	:	3731
Examiner	:	Bradford C. Pantuck

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

The undersigned hereby certifies that the following documents:

1. Response to Restriction Requirement; and,
2. Postcard receipt;

relating to the above application, were deposited as "First Class Mail" with the United States Postal Service, addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313, on May 6, 2004.

Date: 5/6/04 Kathy Cedar
Mailer

Date: May 6, 2004 William A. Munck
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RESPONSE TO RESTRICTION REQUIREMENT

A Restriction Requirement was mailed in the present patent application on April 6, 2004 with a time period for response ending on May 6, 2004.

In response to the Restriction Requirement, the Applicants provisionally elect the claims of Group I, Claims 1–21 and Claims 31-61 WITH TRAVERSE. Claims 31-61 were added to the patent application by a Preliminary Amendment dated April 28, 2003. Page 1 of the Restriction Requirement (the Office Action Summary page) states that Claims 1-61 are pending in the application and that Claims 1-61 are subject to a restriction and/or election requirement. Because Claims 31-61 are all directed to a surgical tool Claims 31-61 are properly included in Group I.

The Restriction Requirement characterizes Claims 1–21 and Claims 31-61 (Group I) as drawn to "a surgical tool with a blade" and Claims 22-30 (Group II) as drawn to "a method of cutting scleral tissue." (Restriction Requirement, Page 2). The Applicants respectfully submit that the Restriction Requirement provides no factual basis for asserting either independence or distinctness of these claims. The Restriction Requirement makes the following statements:

> Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process (MPEP § 806.05(e)). In this case the apparatus can be used for a different process, such as cleaning plaque from a stenosed blood vessel/artery/heart. (Restriction Requirement, Page 2).

A restriction requirement must provide the particular factual basis for asserting that restriction is necessary:

> The particular reasons relied on by the examiner for holding that the inventions as claimed are either independent or distinct should be concisely stated. A mere statement of conclusion is inadequate. The reasons upon which the conclusion is based should be given. (MPEP § 816, p. 800-56 (8th ed. rev. 1 February 2003)).

The Restriction Requirement fails to provide such a factual basis (as opposed to a "mere statement of conclusion") indicating why the claims recite patentably distinct inventions – that is, a factual basis for asserting that: "the apparatus can be used for a different process." The Examiner does not identify how the allegedly "materially different process" of cleaning plaque from a stenosed blood vessel/artery/heart can be performed by the surgical tool as claimed in Claims 1-21 and Claims 31-61.

The Applicants respectfully traverse the Examiner's conclusion for the following reasons. Restriction is only proper where the claims are independent or distinct. MPEP § 806. In passing on questions of restriction, the claimed subject matter must be compared in order to determine distinctness and independence. MPEP § 806.01, p. 800-39. The Restriction Requirement concedes that the claims are not independent but are related ("Inventions II and I are related as process and apparatus for its practice") (Emphasis added) (Restriction Requirement, Page 2).

Claim 1 is directed to a surgical tool as follows:

> 1. A surgical tool for making an incision in scleral tissue of an eye comprising:
>
> a rotatable blade capable of being rotated by said surgical tool through said scleral tissue of said eye to make an incision having the form of a scleral pocket that is capable of receiving a scleral eye implant prosthesis.

Claim 22 is directed to a method for making an incision in scleral tissue of an eye that requires the use of the surgical tool as claimed in Claim 1:

> 22. A method for making an incision in scleral tissue of an eye to form a scleral pocket to receive a scleral eye implant prosthesis, said method comprising the steps of:
>
> placing on said scleral tissue of said eye a rotatable blade of a surgical tool, said rotatable blade capable of being rotated by said surgical tool through said scleral tissue of said eye to make an incision having a form of a scleral pocket;
>
> holding said scleral tissue to restrain movement of said scleral tissue;
>
> rotating said rotatable blade in a forward direction to cause said rotatable blade to pass through said scleral tissue to form said incision having said form of a scleral pocket; and
>
> rotating said rotatable blade in a reverse direction to remove said rotatable blade from said incision.

From the foregoing, the Applicants respectfully submit that it is clear that only a surgical tool of the type claimed in Claim 1 can perform the method as claimed in Claim 22. That is, there is not "another materially different apparatus" that can perform the method of the invention as claimed in the Group II claims. Furthermore, the apparatus of the Group I claims can not be used for a different process, such as cleaning plaque from a stenosed blood vessel/artery/heart. The surgical tool of the Group I claims must be located outside of a blood vessel. The surgical tool of the Group I claims can not reach plaque that is located inside a blood vessel without cutting through the external surface of the blood vessel. This would result in an uncontrolled hemorrhage of blood. The surgical tool of the Group I claims is a hand held external tool that is too large to be employed inside a blood vessel or inside an artery or inside a heart.

Therefore, the Restriction Requirement accordingly has failed to establish that the apparatus as claimed in Claims 1-21 and Claims 31–61 could be used for another materially different process than the method as claimed in Claims 22–30.

With regard to the assertion that "Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper," the Restriction Requirement fails to provide any factual basis for such conclusion.

With respect to distinctness of the Group I claims (Claims 1–22 and Claims 31-61) from the Group II claims (Claims 22-30), the Restriction Requirement fails to satisfy any of the requirements for restricting the claims of the patent application. Accordingly, the Applicants respectfully request that the restriction be withdrawn.

SUMMARY

If any issue arises, or if the Examiner has any suggestions for expediting allowance of this application, the Applicants respectfully invite the Examiner to contact the undersigned at the telephone number indicated below or at ***wmunck@davismunck.com.***

The Commissioner is hereby authorized to charge any additional fees connected with this communication or credit any overpayment to Deposit Account No. 50-0208.

Respectfully submitted,

DAVIS MUNCK, P.C.

Date: May 6, 2004

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